

	Technical Information	730-081-EN		V06
	Incorrect colour change of steam process indicators because of superheated steam	Created	12.02.2007	JM
		Changed	02.09.2021	KP
		Checked	02.09.2021	UK
		Released	02.09.2021	UK
File no.: 1.1				

When GKE process indicators according to EN ISO 11140-1 type 1 for steam sterilization are used, sporadically an insufficient colour change of the chemical indicator may occur, showing a lighter blue-green colour. There may be several reasons for this problem, but the most frequent reason is the presence of superheated steam.

The boiling temperature of water is depending on the pressure. The boiling temperature at normal pressure of water is approx. 100°C, that means steam with a temperature of 100°C condenses on all surfaces colder than the steam itself. At higher pressure of 2 or 3 bar absolute, the boiling temperature of water increases to 121°C or 134°C. That means that in the sterilizer chamber steam condenses to water on all surfaces colder than the steam itself, e.g. on or in the packages and instruments. To obtain a successful sterilization, wetness of all surfaces is essential, because the sterilizing agent in a steam sterilization process is water in the liquid phase.

If steam at 3 bar with a temperature higher than 134°C is present, this can be caused by heated walls which have a higher temperature than the steam or the steam entering the chamber, which has just passed through a pressure reducing valve, has a temperature higher than 134°C. If steam gets in contact with the surface of a big object, e.g. a sterilization container, the container is cooling down steam in contact until the condensation temperature is reached. So condensation takes place and all surfaces get wet. If steam gets in contact with a label on top of a pack or a free hanging container seal, which only has a low weight, the superheated steam is not cooled down sufficiently and superheated steam circulates around the indicator without condensation, the indicator will remain dry, changing the colour to blue-green only. In the GKE application laboratory those colour changes have been reproduced in tests with superheated steam.

You can test this effect yourself placing an indicator in a container with heavy load. Usually even in superheated steam inside there are saturated steam conditions. In there, the same indicator will change to brown/black while the indicator on top of the package is changing to blue-green, if superheated steam is present.

The unsatisfying colour change of the process indicator is not a subject to judge the result of the sterilization, if it is a sporadic effect, that means if in a batch only particular labels or seals are affected while the other ones have changed correctly, and if the used batch monitoring system (BMS), consisting of a hollow PCD (= Process Challenge Device) and suitable indicator strips, verifies successful steam penetration of complex hollow devices.

The problem can be solved completely, if the presence of superheated steam in the chamber can be technically eliminated.